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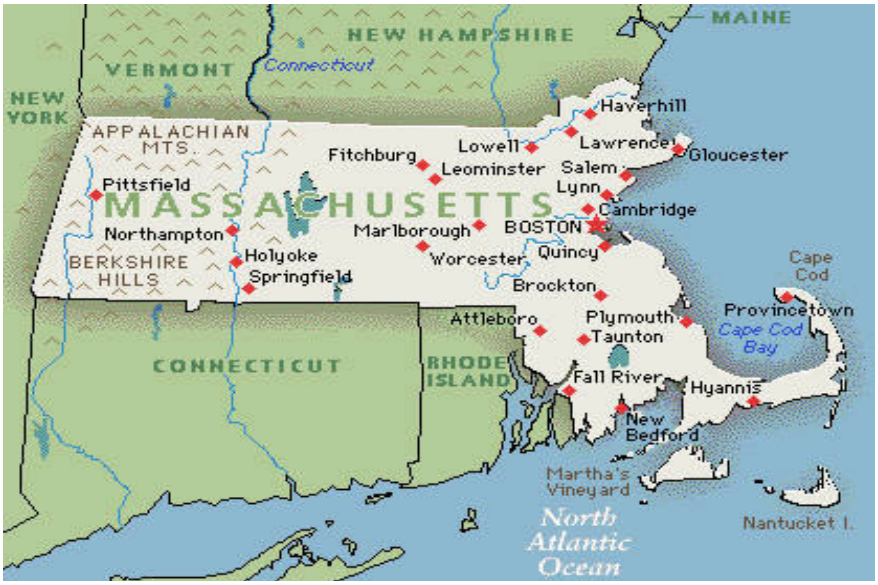

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The Reporter

A publication of
the Division of Food and Drugs, Food Protection Program
and the Division of Community Sanitation

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The Reporter is published by the Massachusetts Department of Public Health, Division of Food and Drugs, Food Protection Program and the Division of Community Sanitation. For further information on these and other topics, Food Protection Program staff may be reached by calling 617-983-6712 and Division of Community Sanitation staff may be reached by calling 617-983-6762.

This publication is sent to all Boards of Health in the Commonwealth. It is requested that a copy be circulated to all board members and interested employees. Other interested individuals and agencies may request a copy by contacting the Editor.

Please address all correspondence to: Joan L. Gancarski, Editor; The Reporter; Division of Food and Drugs; Massachusetts Department of Public Health; 305 South Street; Jamaica Plain, MA 02130, Telephone: 617-983-6764, e-mail: joan.gancarski@state.ma.us, or FAX: 617-983-6770 ❖

Letter from the Directors:

Paul J. Tierney, Division of Food and Drugs, Food Protection Program
Howard S. Wensley, M.S., C.H.O., Division of Community Sanitation

In the last few months both the Division of Food and Drugs Food Protection Program (FPP) and the Division of Community Sanitation (DCS) have continued to be actively involved in writing and revising public health regulations.

- The Public Health Council approved the Fish and Fisheries Products regulation, updating 105 CMR 533.000. This revised regulation was submitted to the State Secretary of State Office, and was officially promulgated on October 26, 2001. Copies of the regulation are available through the State House Bookstores: 617-727-2835.
- In conjunction with regulatory reform, legislation was filed in the state legislature by the to transfer licensing and permitting authority of instate wholesale bottled water processing, dairy plant facilities and wholesale frozen dessert operations from local Boards of Health to the Division of Food and Drugs.

  An advisory committee has been convened on the bottled water processing regulation and the committee is producing a draft to be discussed at public hearings.

  An advisory committee will be convening later this year to draft regulations on on the wholesale frozen dessert operations.
- During the winter, DCS will be working on amending regulations for infectious waste and juvenile detention centers.

The beach season appears to have gone well. The DCS is in the process of collection and analyze the test results. This should assist us in determining problem areas and in cooperation with the municipalities and others ate agencies to develop corrective action.

During the season, 288 beach closings representing 156 beaches were reported to the Massachusetts Department of Public Health. .

Finally, formal budget action is still awaiting for reimbursement of beach testing activities.

The Division will also be developing a housing training program in cooperation with the Massachusetts Environmental Health Association (MEHA).

The FPP was recently notified that it had received an Innovative Food Safety Grant from the U.S. FDA. The grant was proposed to develop standardized instructions for local and state retail food regulators in the initiation, evaluation and verification of HACCP and risk-control plans in retail food establishments.

In conjunction with the MDPH Division of Communicable Disease, the FPP was

awarded a U.S. Centers for Disease Control and Prevention grant to improve the ability of local boards of health to conduct foodborne illness surveillance. A component of the grant includes the creation of guidelines as well as the development and presentation of training for foodborne illness investigations. The FPP has hired Frauke Argyros, M.S to fill this position .

In September 2001, Robert Altobelli left his position as Supervisory Inspector of the Dairy Plant Inspection Unit to join the U.S. FDA. Active recruitment and search is on-going in an attempt to the fill this vacated position.

Other staffing changes include Kim Foley re-joining the FPP as the Bottled Water Licensing Coordinator.

Food Sample Submission Information and Procedures

Introduction

The Division of Food and Drugs (DFD) and the State Laboratory Institute (SLI) works with regulatory agencies to aid in the investigation of suspect foodborne illness complaints, food injury complaints and food adulteration complaints. The two labs at the SLI that analyze food samples are the Food Microbiology Laboratory (Food Lab) and the Analytical Chemistry Laboratory (also referred to as the Environmental Lab). Each laboratory has its own sphere of expertise and range of tests that it can perform. This guideline will describe the capabilities of both laboratories and outline the proper indications and procedures for submitting samples. This guideline is intended to provide state and local regulatory officials with an introduction to these two laboratories and to provide basic information for health agents to use when submitting samples. Because many situations are unique and often complex, the Division of Food and Drugs must be contacted prior to submitting all samples.

Important Phone Numbers

Division of Food and Drugs: 617-983-6712 617-983-6770 (fax)
Food Microbiology Laboratory: 617-983-6610
Analytical Chemistry Laboratory: 617-983-6653 or 617-983-6658

Food Microbiology Laboratory

Before submitting samples, contact the Division of Food and Drugs at 617-983-6712.

Available Tests

When submitting samples for analysis, it is the responsibility of the submitter to request the appropriate tests. In order to know what tests to request, the investigator should consider epidemiological information, results of the environmental investigation and results of clinical testing if available. Chapter 2 of the Foodborne Illness Investigation and Control Reference Manual (http://www.state.ma.us/dph/fpp/refman.htm) contains information which can aid in this determination. In addition, the DFD must be contacted prior to submission and can help determine which tests would be appropriate. The following is a list of the tests which the Food Laboratory has the capability to perform.

Procedures involving "Counts":

? Standard Plate Count (SPC), also called Aerobic Plate Count (APC)
? Total coliform count
? Fecal coliform count, if total coliforms are detected
? Staphylococcus aureus count
? Bacillus cereus count
? Viable yeast count
? Viable mold count
? Clostridium perfringens count
? Total E. coli count (special request)

Procedures involving detection of pathogens (viable organisms):

? Clostridium botulinum (special request)
? Salmonella spp.
? E.coli O157:H7
? Campylobacter spp.
? Shigella spp.
? Vibrio spp.
? Yersinia spp.
? Listeria monocytogenes
? Shiga toxigenic E. coli other than O157:H7 (STEC) (special request)

Procedures involving the detection of toxins:

? Paralytic Shellfish Poisoning (PSP)
? Botulinal toxin (special request)
? Shiga toxin (special request)

Procedures involving sterility confirmation:

? Canned goods
? Infant food

Procedures involving filth analysis:

? Extraneous material
? Insect identification
? Phosphatase test for rodent droppings
? Rodent urine (ultraviolet light)

Note: The Food lab cannot test for viruses or parasites in food or beverages.

When to test:

Microbiological testing:
Not all food samples collected in response to a complaint are appropriate samples for microbiological testing. In general, the following are appropriate samples for analysis:

- samples associated with investigations of suspect foodborne illness involving two or more people ;
- samples associated with a single *laboratory confirmed* case if the suspect food was eaten within the incubation period;
- samples associated with any confirmed or suspect case of botulism;
- raw ground beef or meat, if associated with a confirmed case of *E. coli* O157:H7;
- suspect illnesses related to baby foods or formulas.

Bacterial testing is most appropriate when there is a high index of suspicion that the food sample in question did in fact make the complainant ill. In situations in which a clinical laboratory confirmed the diagnosis, the food sample should be tested for that organism. Such laboratory confirmed cases provide the best chance for determining whether the suspect food was the cause of the illness.

Unfortunately, most of the foodborne illness complaints are not laboratory confirmed, and therefore sample testing is more challenging. In unconfirmed cases, the investigator must make an educated guess as to the most likely cause of the illness and request that the Food Lab perform the appropriate test(s). The DFD and/or the Food Lab must be consulted prior to submitting the food sample for analysis to assist in determining the appropriate tests.

When analyzing samples associated with an unconfirmed illness, the Food Lab will always do a Standard Plate Count (SPC) and Total Coliform Count. If coliforms are found in the sample, then a fecal coliform test will also be performed. These tests can never definitively determine whether the food sample in question caused the illness because these tests are not specific for pathogens. At best, these tests provide indirect evidence for poor food handling practices and/or contamination of food product. When evaluated in conjunction with the findings of an environmental investigation, a high SPC or coliform count may support the conclusion that poor food handling practices occurred. Because complaint samples are usually consumer samples leftover from the suspect meal, there is always the possibility that growth of aerobic bacteria and/or coliforms occurred after the food left the food service establishment and before it arrived at the food lab. It is impossible to draw any conclusions about where contamination and growth may have occurred without a thorough environmental investigation and detailed chain of custody information.

It is always preferable to test a sample of the food that the complainant actually ate. If the consumer's leftover sample is not available but the establishment has food that was prepared the same day, that would also be an acceptable sample. It should be noted that testing of raw foods is not recommended unless a specific pathogen is confirmed or strongly suspected or there is good reason to suspect *E. coli* O157:H7. (Raw ingredients, especially meats, contain relatively high levels of non-pathogenic bacteria. Non-specific analyses such as SPC and coliforms are not likely to be informative.) Because such foods are typically cooked, finding high SPCs or coliforms in the raw product is usually of no consequence.

The Food Lab will test any baby food or formula which is associated with a foodborne illness complaint. Even if the case is not laboratory confirmed, the vulnerability of this population and the potential serious consequences of contamination warrant taking all such complaints very seriously.

Filth analysis:
Filth analysis involves examining a food for the presence of foreign objects. The Food Lab will do a filth analysis even if no injury or illness has occurred. The suspect object, however, should be of a serious enough nature that injury or illness might have occurred. In addition, when the presence of the object indicates a violation of good retail practices or good manufacturing practices, it may be appropriate to submit the food for examination.

If the identity of an object is obvious, such as a band-aid or a needle, the local health agent can attest to the identity of the object and submission of the object to the Food Lab for verification should not be necessary. If the local health agent feels strongly that a second opinion is warranted, then the sample may be submitted to the Food Lab after consultation with DFD or the lab.

Note:
? ***The Food Lab cannot test for the presence of blood in or on food or foreign objects.***
? ***The Food Lab does not test for HIV or hepatitis viruses in or on food or foreign objects.***

Procedure for Collecting Samples:

- If possible, leave the food sample in its original container or in the container in which the consumer has placed it. This will reduce the chances of introducing additional contamination to the sample. However, if the sample is very large or the container is not secure, the sample or a portion of it will need to be transferred to a new container.
- Use sterile containers and do not touch the inside of the container. However, if a sterile container is not available, any clean container which can be tightly sealed may be used.
- Use sterile utensils, tongs, spoons, etc, if available. If not available, other clean utensils can be used.
- Make sure caps are tight to prevent leakage.
- If multiple samples are suspected, such as the various components of a meal, pack each separately. Do not commingle individual samples.
- Whirlpack bags can be used for solid foods but should not be used for liquids.
- Collect adequate amounts: 100-150 grams or milliliters (4-6 oz) if available.
- When collecting liquid samples, fill the container no higher than ¾ full in order to allow for proper mixing of the sample.
- When collecting water from spigots, let the water run for 2 minutes before collecting.
- Label all samples clearly with identifying information. Use waterproof ink and labels.
- If the sample is refrigerated, keep it cool (<41° F) during storage and transportation. Gel packs are usually adequate for transporting samples.
- If the sample is frozen, keep it frozen.
- If a perishable food is at room temperature when collected, refrigerate and keep cold (< 41° F). Any food submitted for microbiological analysis should be kept refrigerated until submitted including maintaining temperature control during transport.
- If a sample for microbiological testing cannot be submitted for several days the sample can be frozen. It should be kept in mind that freezing may injure bacterial cells and can hinder the ability to detect microorganisms and is not generally recommended.

Procedure for Submitting Samples:

- Call the DFD prior to submitting sample.
- Samples must be submitted by the local board of health. Consumers should never be instructed to drop off the samples at the SLI.
- Maintain temperature control of the sample.
- Fill out the sample submission form and give to a Food Lab bacteriologist when the samples are dropped off. Do not just leave them in the lab!
- Indicate which tests are requested.
- Chain of custody should be described on a separate form (i.e., the narrative page of an inspection report form).
    - ? Indicate when (date and time), where and from whom the sample was obtained.
    - ? Describe where the sample had been kept and what type of container it had been stored in, (i.e., plastic bag in consumer's refrigerator).
    - ? Describe where and how the sample was held while in the custody of the board of health and how it was transported to the lab (i.e. if put in different container, if held in the refrigerator in the office, if placed in cooler with gel packs for transport, etc.).
- If the food sample is associated with a suspect illness, submit a Foodborne Illness Complaint Worksheet. The Worksheet can either be submitted with the sample or faxed to the DFD prior to sample submission.
- The sample must be submitted as soon as possible, ASAP.
    - ? It is preferable to submit the sample in-person or by courier.
    - ? Overnight mail can be used if the sample is packed with sufficient gel packs to keep it cool (sample should be double bagged to insure it does not become contaminated during transport).
    - ? Regular mail is not appropriate for any sample being submitted for microbiological testing. (Regular mail may be acceptable for filth evaluation in non-perishable foods.)

- If the sample is a pre-packaged food or beverage, obtain the name and address of the manufacturer and/or distributor. Product codes, expiration or sell-by dates and size and type of packaging are also needed to determine which lots might be affected. (UPC codes are not sufficient. Although they identify the product, they do not contain lot-specific information about when and where the product was made. The lot-specific codes are usually stamped or embossed on the package by the manufacturer.)
- When the suspect sample is a pre-packaged food or beverage, an unopened container, preferably of the same lot number, should also be submitted.

Note: If the correct sample submission procedures are not followed, the Food Lab may not be able to analyze the food sample.

Analytical Chemistry Laboratory (Environmental Laboratory)

Before submitting samples, contact the Division of Food and Drugs at 617-983-6712.

Available Tests:

The following is a partial list of the tests which the Analytical Chemistry Lab can perform. It is the responsibility of the person submitting the sample to request the appropriate tests. Because food chemical analysis is very complex, the submitter must consult with the DFD prior to submitting a sample.

Samples will not be accepted without prior approval.

Metals and elements in foods and beverages

- copper
- lead
- arsenic
- mercury
- others as needed

Industrial chemicals

- Pesticides in fruit and vegetables
  - organophosphates
  - organochlorines
  - carbamates
- Rodenticides
- Polychlorinated biphenyls (PCBs)
- Petroleum distillates (fuels)

Unusual tastes or odors in foods and beverages

- Volatile organic compounds (VOCs)
  - Solvent-like odors in food or beverages
  - ? Benzene
  - ? Ethylbenzene
  - ? Toluene
  - ? Xylene
  - ? Others as needed
- Surfactant screen
  - Anionic or cationic determination of surfactant

Preservatives in Beverages (labeling issues)

- Benzoic acid
- Sorbic acid

Sulfite testing in food products

Biogenic amines (histamine) testing in fish for scombroid poisoning

Seafood toxins

- PSP
- Domoic acid

Testing products for evidence of tampering

- Organoleptic testing
- Pill identification (medications)
- Chemical spot tests
- Volatile and semi-volatile comparisons
- pH testing

When to test:

? Injury or illness due to suspect foreign chemical substance in food: ONE CASE is often enough to warrant an examination
? Pills or capsules found in food or beverage
? Unusual chemical odor or taste with or without injury or illness
? Finfish samples associated with histamine (scombroid) poisoning
? Shellfish associated with suspect PSP or domoic acid poisoning

Before submitting samples, local health agents must first call DFD or the Analytical Chemistry Lab to discuss the testing procedures and correct submission of samples. The lab cannot do blind screens so samples must be submitted with enough information to narrow the possibilities of things for which to test. The lab will need a copy of the complaint with all relevant case and environmental information. If the complaint involves an illness, then the Foodborne Illness Complaint Worksheet should be completed and submitted with the sample. There is no sample submission form for the Analytical Chemistry Lab, therefore a detailed narrative, including chain of custody information, should be submitted with the sample.

When chemical contamination is suspected, a precise description of the taste and smell of the food or beverage can provide useful clues to the identity of the contaminant. When illness or injury results, a full description of the onset time, symptoms and any medical diagnosis also provide important information. In some cases, such as histamine poisoning, the symptoms experienced by the complainant can be diagnostic.

In addition, a thorough environmental investigation is necessary and can be very helpful. The environmental investigation should focus on possible sources of chemical contamination. It is also very useful to be able to compare the foreign substance in the food with chemicals found on the premises where the food was prepared or stored. Samples of possible chemical contaminants should be submitted with or soon after submission of the suspect food.

Procedure for Collecting Samples

- Samples should be kept in the original container if possible. If the sample cannot be submitted in the original container or the original container cannot be shut tightly, consult the lab for information on what type of container is appropriate (some samples will need to be stored in glass, some in plastic depending on the suspect contaminant)
- Samples should be kept in containers that can be sealed to prevent leakage of liquids or loss of volatile substances.
- Relevant control samples should be collected (see below).
- Samples should be submitted as soon as possible. If there is likely to be a delay, consult the lab about whether the sample should be frozen or refrigerated. If the lab or DFD cannot be contacted right away, put the sample in a container which can be tightly closed and place in the refrigerator.
- **Histamine:** Finfish samples for histamine testing should be kept at or below 41°F and submitted as soon as they are collected. **If there is any delay, even a few hours, the sample should be frozen.**

Procedure for Submitting Samples

For correct sample submission procedures, it is very important to consult Division of Food and Drugs or the Analytical Chemistry Lab prior to submitting samples.

- Submit a detailed description of the complaint with the sample. Include symptoms, diagnoses, taste, odor and any other descriptive information.
- Submit chain of custody information.
- Samples must be submitted by a representative of the local board of health. Consumers should never be instructed to drop off the samples at SLI themselves.
- Submit the results of the inspection of the implicated retail establishment where the food was prepared or stored.
- Submit control samples (see below).
- Maintain temperature control of the sample.
- NOTE: If the sample is a pre-packaged food or beverage, obtain the name and address of the manufacturer and/or distributor. Product codes, expiration or sell-by dates and size and type of packaging are also needed to determine which lots might be affected. (UPC codes are not sufficient. Although they identify the product, they do not contain lot-specific information about when and where the product was made. The lot-specific codes are usually stamped or embossed on the package by the manufacturer.)

  When submitting pre-packaged foods, provide an unopened package of the exact same product in the same type and size package and from the same lot number as the suspect product. This sample is analyzed to determine if there is a contamination problem at the manufacturing facility.

Control samples:
The Analytical Chemistry Laboratory needs control samples to run many of its tests and will not analyze samples if a control is not provided. For pre-packaged foods, a control sample is an unopened package of the suspect food which is very likely to be free of contamination. The control must be the exact same product in the same type and size package as the suspect food.

The control sample should be from a different lot number than the suspect sample.
If the suspect food is not pre-packaged, then the control sample should be obtained from the same establishment which produced the suspect sample. The control should be the exact same product as the suspect food but from a different batch.

Whenever fish is submitted for histamine testing, a control piece is always required. If the control is from the same establishment as the complaint, it should be from a different lot than the suspect sample. If the establishment does not have any fish from a different lot, obtain the control from a different establishment.

Controls are necessary because foods and beverages are chemically complex. The test results from the suspect sample are compared against the results from the control sample. Differences between the two samples would be considered significant. In addition, the control provides evidence that any unusual findings in the suspect sample are not due to chemist's misinterpretation or instrumental error but are in fact true findings.

Note on Testing for Allergens:

With the exception of sulfites, the State Laboratory does not have the capability to test for allergens in food. While allergic reactions can be serious and are a public health concern, they do not pose any regulatory issues unless the concern is that a food has been mislabeled. Failure to declare the presence of peanuts, soybeans, milk, eggs, fish, crustaceans, tree nuts, or wheat is a major concern because these eight allergens are thought to cause over 90 percent of all allergic reactions from food. If such a situation is suspected, the DFD should be notified immediately. If necessary, samples may be able to be sent to an outside lab for testing.

Quick Guide to Food Sample Submission Information and Procedures

The Division of Food and Drugs must be contacted prior to submitting all samples.

Phone Numbers
Division of Food and Drugs: 617-983-6712 617-983-6770 (fax)
Food Microbiology Lab: 617-983-6610
Analytical Chemistry Laboratory: 617-983-6653

State Laboratory Institute
305 South Street
Jamaica Plain, MA 02130

	Food Microbiological Laboratory	Analytical Chemistry Laboratory
Available Tests	**Procedures involving "Counts":** ➢ Standard Plate Count (SPC) also called Aerobic Plate Count (APC) ➢ Total coliform count ➢ Fecal coliform count ➢ Staphylococcus aureus count ➢ Bacillus cereus count ➢ Viable yeast count ➢ Viable mold count ➢ Clostridium perfringens count ➢ Total E. coli count (special request) **Detection (viable organisms):** ➢ Clostridium botulinum (special request) ➢ Salmonella spp. ➢ E.coli O157:H7 ➢ Campylobacter spp. ➢ Shigella spp. ➢ Vibrio spp. ➢ Yersinia spp. ➢ Listeria monocytogenes ➢ Shiga toxigenic E. coli other than O157:H7 (STEC) (special request) **Toxin testing:** ➢ Paralytic Shellfish Poisoning (PSP) ➢ Botulinal toxin (special request) ➢ Shiga toxin (special request) **Sterility confirmation:** ➢ Canned goods ➢ Infant food **Filth analysis:** ➢ Extraneous material ➢ Insect identification ➢ Phosphatase test for rodent droppings ➢ Rodent urine (ultraviolet light) **Note**: The Food lab cannot test for viruses, parasites or the presence of blood in food or beverages.	**Metals and elements in foods and beverages** ➢ copper ➢ lead ➢ arsenic ➢ mercury ➢ others as needed **Industrial chemicals** ➢ Pesticides in fruit and vegetables o organophosphates o organochlorines o carbamates ➢ Rodenticides ➢ Polychlorinated biphenyls (PCBs) ➢ Petroleum distillates (fuels) **Unusual tastes or odors in foods and beverages** ➢ Volatile organic compounds (VOCs) o Solvent-like odors in food or beverages • Benzene • Ethylbenzene • Toluene • Xylene • Others as needed o Surfactant screen ▪ Anionic or cationic determination of surfactant **Preservatives in Beverages (labeling issues)** ➢ Benzoic acid ➢ Sorbic acid **Sulfite testing in food products** **Biogenic amines (histamine) testing in fish for scombroid poisoning** **Shellfish toxins** ➢ PSP ➢ Domoic acid **Testing products for evidence of tampering** ➢ Organoleptic testing ➢ Pill identification (medications) ➢ Chemical spot tests ➢ Volatile and semi-volatile comparisons ➢ pH testing
Appropriate Samples	➢ Samples associated with investigations of suspect foodborne illness involving 2 or more people ➢ Samples associated with a single *laboratory confirmed* case if the suspect food was eaten within the incubation period ➢ Samples which may be associated with one or more cases of botulism ➢ Raw ground beef or meat if associated with confirmed case of E. coli O157:H7 ➢ Suspect illnesses related to baby foods or formulas	➢ Injury or illness due to suspect foreign chemical substance in food: ONE CASE is often enough to warrant an examination ➢ Pills or capsules found in food or beverage ➢ Unusual chemical odor or taste with or without injury or illness ➢ Finfish samples associated with histamine (scombroid) poisoning ➢ Shellfish associated with suspect PSP or domoic acid poisoning

Quick Guide to Food Sample Submission Information and Procedures

Sample Collection Procedures	➢ Keep the sample in the original container if possible. ➢ Use sterile containers and do not touch the inside of the container. However, if a sterile container is not available, any clean container which can be tightly sealed may be used. ➢ Use sterile utensils, tongs, spoons, etc, if available. If not available, other clean ustensils can be used. ➢ Make sure caps are tight to prevent leakage. ➢ If multiple samples are suspected pack each separately. Do not commingle individual samples. ➢ Whirlpack bags can be used for solid foods but should not be used for liquids. ➢ Collect adequate amounts: 100-150 grams or milliliters (4-6 oz) if available. ➢ When collecting liquid samples, fill the container no higher than ¾ full in order to allow for proper mixing of the sample. ➢ When collecting water from spigots, let the water run for 2 minutes before collecting. ➢ Label all samples clearly with waterproof ink and labels. ➢ If the sample is refrigerated, keep it cool (<41° F) until submission. Gel packs are usually adequate. ➢ If the sample is frozen, keep it frozen. ➢ Perishable foods should be refrigerated and kept cold (< 41° F). ➢ If a sample for microbiological testing cannot be submitted for several days the sample can be frozen.	➢ Keep the sample in the original container if possible or consult DFD or lab about appropriate container. ➢ Make sure caps are tight to prevent leakage. ➢ Collect control samples. ➢ Submit samples as soon as possible. If there is a delay, consult the lab about whether the sample should be frozen or refrigerated. When in doubt, keep the sample in the refrigerator. ➢ **Histamine:** Finfish samples should be submitted right away or frozen immediately.
Sample Submission Procedures	**Call DFD prior to submitting sample.** ➢ Fill out sample submission form and give to Food Lab when samples are dropped off. ➢ Samples should be submitted to SLI by the local board of health. Consumers should not be told to drop off samples. ➢ Maintain temperature control of sample. ➢ Chain of custody should be described on a separate form (ie. the narrative page of an inspection report form) ➢ If the food sample is associated with suspect illness, submit Foodborne Illness Complaint Worksheet. ➢ The sample must be submitted ASAP, preferably in-person or by courier. Regular mail is not appropriate except for filth evaluation in non-perishable foods. Overnight mail can be used if sample is packed with sufficient gel packs to keep it cool. ➢ For pre-packaged foods or beverages, obtain the name and address of the manufacturer and/or distributor, product code, expiration or sell-by date and size and type of packaging. ➢ For pre-packaged foods or beverages, an unopened container of the same lot number should be submitted.	**Call DFD prior to submitting sample.** ➢ Submit a detailed description of the complaint with the sample. ➢ Submit the results of the environmental investigation. ➢ Submit chain of custody information. ➢ Samples should be submitted to SLI by the local board of health. Consumers should not be told to drop off samples. ➢ Maintain temperature control of sample. ➢ Submit the sample in the original container if possible or consult DFD or lab about appropriate container. ➢ Control samples MUST be submitted with the suspect sample. ➢ For pre-packaged foods or beverages, obtain the name and address of the manufacturer and/or distributor, product code, expiration or sell-by date and size and type of packaging.

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH SAMPLE SUBMISSION FORM DIVISION OF FOOD & DRUGS OTHER_____

Signature of Inspector delivering sample to Laboratory:	Laboratory Number(s):
Sample Numbers of Inspector who collected samples:	Date Collected:
Name of **Establishnent/Plant/Individual**-Include Address and Phone Number: Sample origin:	Date Received in Laboratory:_____ Time:_____ Initials:_____ Condition received in Lab.: On ice_____ Frozen _____ Room Temp._____ Other: _____
Send results to: Name/Title: Address: Phone: Fax:	Date results submitted to Supervisor:

SPECIFIC INSTRUCTIONS: ASSIGNMENT: DATE:_____

Reason for sample submission: Inspection:____ Salvage:____ Embargo: ____ (Tag #)

Complaint:____ General Complaint #_____ or Foodborne Illness:____ Foodborne Illness Complaint # _____ Date purchased:_____

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH STATE LABORATORY INSTITUTE FOOD MICROBIOLOGY LABORATORY

PRODUCT INFORMATION **LAB RESULTS**

Lab. Number	Inspector Number	Sample Description	S'	Description Type of Container Sealed/Open	Code/ Date	Net Wt/Vol Or Gross Wt/Vol	Results					

S': Indicates source of sample: Consumer-(C), Retail-(R), Manufacturer-(M), Distributor-(D), Follow-up-(F), Other-(O) <10 = not found at 1:10 <100 = not found at 1:100 <1000 = not found at 1:1000

*** = Violation NF = Not Found NA = Not Applicable ** Results suggest further investigation of ingredients or food handling procedures is recommended.**

Date analysis completed:_____ Date Reported:_____ Analyst(s):_____ Reviewed By:_____ Leftover sample in lab: Yes:____ No:____

REMARKS:

SAMPLE CONTINUATION SHEET

PRODUCT INFORMATION							LAB RESULTS
Lab. Number	**Inspector Number**	**Sample Description**	**S'**	**Description Type of Container** Sealed/Open	**Code/ Date**	**Net Wt/Vol Or Gross Wt/Vol**	**Results**

S': Indicates source of sample: Consumer-(C), Retail-(R), Manufacturer-(M), Distributor-(D), Follow-up-(F), Other-(O) <10 = not found at 1:10 <100 = not found at 1:100 <1000 = not found at 1:1000

*** = Violation** **NF = Not Found** **NA = Not Applicable** **** Results suggest further investigation of ingredients or food handling procedures is recommended.**

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MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH SAMPLE SUBMISSION FORM DIVISION OF FOOD & DRUGS OTHER_____

Signature of Inspector delivering sample to Laboratory: John A. Jones	Laboratory Number(s):This Space for State Lab Use Only
Sample Numbers of Inspector who collected samples: JJ100-JJ110/ **or** Leave blank if no inspector number is assigned –the state lab will assign number(s).	Date Collected: 1/3/00
Name of **Establishnent/Plant/Individual**-Include Address and Phone Number: Tasty Steak Restaurant Mr. James Bean (consumer/complainant) 500 Maple Street 211 Memorial Drive Waterbury, MA 02172 New City, MA 02113 (617) 923-0000 (617) 523-2222	Date Received in Laboratory:_____ Time:_____ Initials:_____ Condition received in Lab.: On ice_____ Frozen _____ Room Temp._____ Other _____This Space for State Lab Use Only
Sample origin: James Bean (consumer/complainant)	
Send results to: Name/Title: Mary Smith, RN Address: Waterbury Board of Health 300 Main Street Waterbury, MA 02172 Phone: (617) 923-0001 Fax: (617) 923-0002	Date results submitted to Supervisor: This Space for State Lab Use Only

SPECIFIC INSTRUCTIONS: This Space for State Lab Use Only ASSIGNMENT: This Space for State Lab Use Only DATE: This Space for State Lab Use Only

Reason for sample submission: Inspection:____ Salvage:____ Embargo: ____ (Tag #) Complaint: X General Complaint #_____

or Foodborne Illness:____ Foodborne Illness Complaint # _ This Space for State Lab Use Only Date purchased: 12/30/99

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH MASSACHUSETTS STATE LABORATORY INSTITUTE FOOD MICROBIOLOGY LABORATORY

PRODUCT INFORMATION **LAB RESULTS**

Lab. Number	Inspector Number	Sample Description	S'	Description Type of Container Sealed/Open	Code/ Date	Net Wt/Vol Or Gross Wt/Vol	Results						
This Space for State Lab Use Only	State Lab Use/ or Assign # JJ100	List detailed description. ex. Cooked meatballs in tomato sauce with onions and mushrooms.	C	Aluminum pie plate covered with aluminum foil	None	Lab Use Only	Lab Use Only	Lab Use Only	Lab Use Only	Lab Use Only	Lab Use Only	Lab Use Only
This Space for State Lab Use Only	State Lab Use/ or Assign # JJ110	Sealed package of raw hamburger 80% lean.	R	Polyfoam Package sealed with plastic wrap	H705 Lot # 1501 Sell by 1/1/00	Lab Use Only	Lab Use Only	Lab Use Only	Lab Use Only	Lab Use Only	Lab Use Only	Lab Use Only

S': Indicates source of sample: Consumer-(C), Retail-(R), Manufacturer-(M), Distributor-(D), Follow-up-(F), Other-(O) <10 = not found at 10^{-1} <100 = not found at 10^{-2} <1000 = not found at 10^{-3}

*** = Violation NF = Not Found NA = Not Applicable ** Results suggest further investigation of ingredients or food handling procedures is recommended.**

Date analysis completed: Lab Use Only Leftover sample in lab: Yes: Lab Use No: Lab Use Date Reported: Lab Use Only Analyst(s): Lab Use Only Reviewed By: Lab Use Only

REMARKS: This Space for State Lab Use Only

Rev.. 9/23/99

FOOD MANAGER CERTIFICATION

Code Requirement

Effective October 1, 2001, the Massachusetts Food Establishment Regulation, 105 CMR 590.003(A)(2) requires food establishments to have a least one person-in-charge (PIC) who is a certified food protection manager. This person must be at least eighteen years of age and be a full-time equivalent on-site manager or supervisor. When the certified PIC is unavailable during operating hours, an alternate PIC must be assigned. The alternate PIC does not require certification; however, this person must be knowledgeable in food safety, foodborne illness prevention and corrective actions.

All food establishments must have a certified food protection manager except the following:

- Temporary food establishments operated by non-profit organizations
- Daycare operations which prepare and/or serve only snacks
- Food establishments which sell only pre-packaged food
- Satellite feeding sites, receiving prepared meals for immediate service
- Food establishments with limited preparation of non-potentially hazardous food
- Food establishments which prepare and serve USDA meat and poultry products containing 120 PPM nitrite and 3.5% brine concentration, such as hotdogs.

Importance of Food Manager Certification

Massachusetts has adopted the food manager certification in order to protect public health and prevent foodborne illness. A certificate implies that the person has knowledge of food safety and the prevention of foodborne illness through the control of risk factors. The certified person must be able to apply this knowledge in day-to-day operations in order to provide consumers with safe food.

Responsibility of the Certified Food Manager

The certified food protection manager is responsible for monitoring and managing all food establishment operations and to ensure that the facility is operating in compliance with food establishment regulations. The certified PIC must be knowledgeable about foodborne illness prevention and must use this knowledge to recognize hazards and take appropriate preventive and corrective actions.

How to Become a Certified Food Protection Manager

A PIC becomes a certified food protection manager by passing one of four accredited examinations. The four accredited examination development companies are:

- Certifying Board for Dietary Managers, 1-800-323-1908
- Experior Assessments, 1-800-200-6241
- National Registry of Food Safety Professionals, 1-800-446-0257
- National Restaurant Association Educational Foundation (ServSafe), 1-800-765-2122

Independent consultants and organizations administer these examinations. Upon passing one of the accredited exams the PIC will receive a certificate and will be in compliance with the certification requirement.

Although training is not a Massachusetts requirement, it is strongly recommended. Most consultants and organizations conduct trainings and then administer an exam. Training is usually needed in order to pass the examination.

How to Find Training

To find food protection training in your area, contact your local board of health. Your local board of health should have information on trainings in the area. Many local boards of health are organizing training and examinations for the food industry. They can also provide a list of trainers in Massachusetts. The four examination organizations may also be contacted to obtain information on trainings in the Massachusetts area.

Prepared by the Massachusetts Department of Public Health, Division of Food and Drugs
October 2000

U.S. Food and Drug Administration
FDA Consumer magazine
September-October 2001
http://www.fda.gov/fdac/departs/2001/501_ltrs.html

Eggs: Sunny Side Up

We've heard that the FDA will not allow restaurants to cook eggs sunny side up after Sept. 1. Is this true? Why is the FDA doing this?

Pam and Steve McFarlan
Burnsville, Minn.

Joseph A. Levitt, director of the FDA's Center for Food Safety and Applied Nutrition, replies:
"There has been some confusion recently in the media over the egg regulation. Some reports have said that the FDA was prohibiting restaurants from serving eggs "sunny side up." That's simply not true. There clearly is the element of consumer choice involved here. There is no FDA requirement that prevents a restaurant from serving eggs in any way a consumer asks for them. What we want to do is to provide the information as to what steps consumers can take to protect themselves. Those who are most likely to be affected by foodborne illnesses are the very young, older people, those with compromised immune systems, and pregnant women. We think that consumers need to know what they can do to minimize any risk. Our new egg handling instructions that will appear on consumer egg cartons beginning this fall say it's important to cook eggs thoroughly and to keep them refrigerated."

See information about shell eggs, see two articles in the Spring/Summer 2001 issue of THE REPORTER :

1. “FDA Finalizes Safe Handling Labels and Refrigeration Requirements for Marketing Shell Eggs”

2. Playing It Safe with Eggs: Food Safety Facts for Consumers

Norwalk-Like Virus Outbreaks at Two Summer Camps ---Wisconsin, June 2001

August 03, 2001 / 50(30);642-3
http://www.cdc.gov/mmwr/PDF/wk/mm5030.pdf
Accessed: August 17, 2001

On June 27 and 28, 2001, the Wisconsin Division of Public Health was notified by two local health departments of outbreaks of gastroenteritis* at two summer recreational camps (camps A and B) in northern Wisconsin. This report summarizes the investigation of these outbreaks, which documents person-to-person transmission of "Norwalk-like virus" (NLV) and underscores the importance of cleaning environmental surfaces and the availability and use of hand-washing facilities at recreational camps.

Camp A opened for the 2001 season with a week of staff training on June 10. During this week, several counselors became ill with fatigue, nausea, vomiting, and diarrhea with illness duration of 24-48 hours. Campers first arrived for a 6-day camp session on June 17 and, within 30 hours of arrival, began having signs and symptoms identical to those experienced by the counselors. A second group of campers replaced the previous campers on June 24. Because many persons became ill in the second group, the camp session was canceled, the campers were sent home, and the local public health department was notified on June 27. During the 3-week period, approximately 80 (20%) of 400 campers and camp staff were ill.

The first case of illness was noted at camp B on June 24 when a child arrived at camp with diarrhea. On June 25, another camper became ill with nausea, vomiting, and diarrhea. During the next 5 days, at least 40 (17%) of the 240 campers and camp staff became ill with identical signs and symptoms lasting 24-48 hours. The campers remained at camp B for the full 1-week session.

Inspection of the camps revealed no substantial problems with food storage or preparation; no leftover foods were available for testing. The campers served themselves family style in a single dining hall at each camp. Ill campers were housed in cabins (camp A) or tents (camp B) with campers who were not ill. Most toilet facilities were pit toilets with hand-washing facilities consisting of cool running water. The camps provided no soap or towels at the pit toilets. Nonmunicipal wells were the source of drinking water at the camps. An environmental survey found no deficiencies with these wells.
Stool specimens were obtained from ill campers and staff at camps A and B. Bacterial enteric pathogen testing was negative and reverse transcriptase polymerase chain reaction for NLV was positive for three of the eight specimens from camp A and two of the four specimens from camp B. Samples of the well water obtained 3 weeks after the outbreaks were negative for fecal coliforms.

The camps, which serve boys aged 10-18 years and are affiliated with the same national youth organization, are located 80 miles apart. They shared no food or personnel and no epidemiologic links were apparent between the camps. Gene sequencing to determine relatedness of the viruses is pending. Although the initial sources of NLV were not discovered, the nature of both outbreaks, particularly the onsets of illness during a several day period and the continuation of the outbreak among separate groups of campers at camp A, indicated the infections were spread within each camp by person-to-person transmission.

NLV can be spread from person-to-person by direct contact, fomites, and aerosols (*1-3*). The close contact of ill and well campers and the rustic setting of the camps probably contributed to person-to-person transmission by contaminated surfaces in the toilet, dining

hall, and living facilities. During June 30-July 1, the washable surfaces at the camps were cleaned with a 10% bleach solution and soap dispensers were added to the hand-washing facilities at camp A. No further cases of gastrointestinal illness were reported at the camps after June 30.

Reported by: L Conlon, Oneida County Health Dept, Rhinelander; K Pranica, L Donart, Oconto County Public Health Div, Oconto; M Proctor, PhD, M Simone, L Lucht, T Boers, JP Davis, MD, Wisconsin Dept of Health and Family Svcs. Div of Applied Public Health Training, Epidemiology Program Office; and an EIS Officer, CDC.

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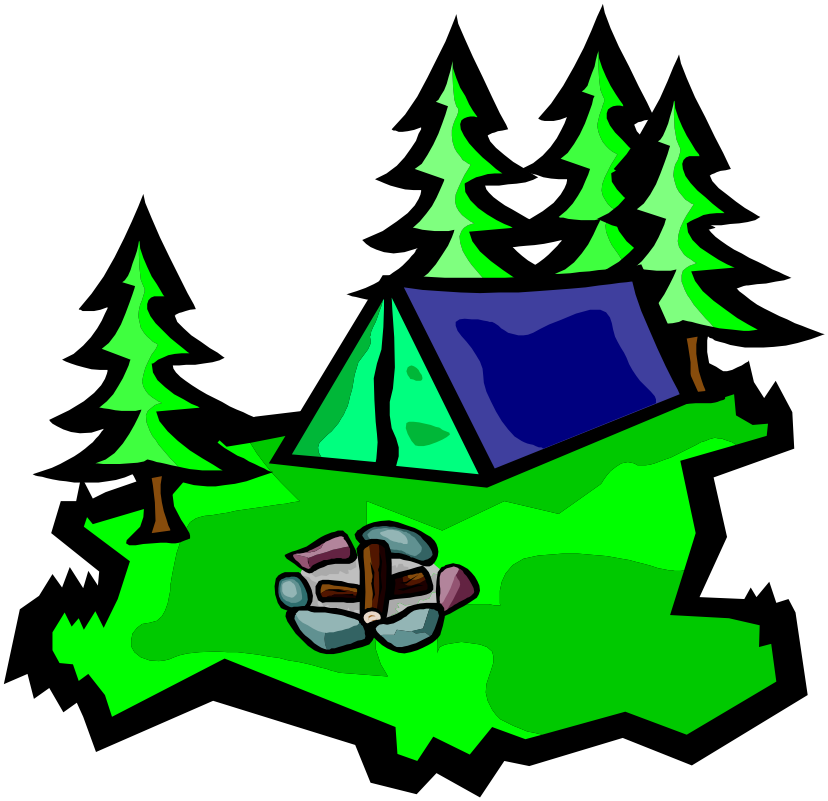
*Defined as nausea, vomiting, or diarrhea in a camper or staff member while at camp A or B during June 10-30, 2001.



Outbreaks of *Escherichia coli* O157:H7 Infections Among Children Associated With Farm Visits --- Pennsylvania and Washington, 2000

April 20, 2001 / 50(15);293-7
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5015a5.htm

During the spring and fall of 2000, outbreaks of *Escherichia coli* O157:H7 infections among school children in Pennsylvania and Washington resulted in 56 illnesses and 19 hospitalizations. Illness was associated with school and family visits to farms where children came into direct contact with farm animals. This report summarizes the findings of investigations of these outbreaks (Figure 1) and includes strategies to reduce the transmission of enteric pathogens from farm animals to children.

Pennsylvania

During September-November 2000, the Montgomery County Health Department (MCHD) identified 51 persons who had diarrhea within 10 days of visiting a dairy farm (farm A) in Montgomery County. Fifteen (29%) persons had either *E. coli* O157 isolated from stool specimens or hemolytic-uremic syndrome (HUS); patients ranged in age from 1-52 years (median: 4 years), 26 (51%) were male, and dates of illness onset ranged from September 4 to November 8. Symptoms reported by the 51 patients included bloody diarrhea (37%), fever (45%), and vomiting (45%); 16 (31%) patients were hospitalized and eight (16%) developed HUS. *E. coli* O157 isolates were indistinguishable by pulsed-field gel electrophoresis (PFGE) and produced both Shiga toxins 1 and 2.

To identify risk factors, CDC, the Pennsylvania Department of Health, and MCHD conducted a case-control study among farm visitors during November 12-19. A confirmed case was defined as diarrhea in a person within 10 days of visiting farm A on or after September 1, with either *E. coli* O157 isolated from stool or HUS. A probable case was defined as diarrhea in a person within 10 days of visiting farm A on or after September 1. Controls also had visited farm A after September 1 but did not develop diarrhea within 10 days of the visit.

Two controls per case were sought by sequential digit dialing and frequency matched by age group (i.e., <1 year, 1-4 years, 5-8 years, 9-12 years, 13-20 years, and ≥21 years). Fifty-one case-patients, or a parent or guardian for young children, and 92 controls were interviewed in the case-control study.

Case-patients were more likely than controls to have had contact with cattle (summary odds ratio [OR]=10.9; 95% confidence interval [CI] =1.7-70.7), an important farm animal reservoir for *E. coli* O157. Activities that promoted hand-mouth contact, such as nailbiting (summary OR=2.5; 95% CI=1.1-5.7) and purchasing food from an outdoor concession (summary OR=2.5; 95% CI=1.1-5.7), were more common among patients. Handwashing before eating was protective (summary OR=0.2; 95% CI=0.1-0.7). All 216 cattle on farm A were sampled by rectal swab, and 28 (13%) yielded *E. coli* O157 with a PFGE pattern indistinguishable from that isolated from patients. The same strain also was isolated from a railing surface. *E. coli* O157 was not isolated from 43 of the other animal species on the farm.

Among the 75,600 persons who visited farm A during the outbreak, most were preschool-aged or school-aged, groups at risk for serious *E. coli* O157 infection (*1*). No separate area was designated for interaction between visitors and farm animals. Visitors could touch cattle, calves, sheep, goats, llamas, chickens, and a pig and could eat and drink while interacting with animals. Handwashing facilities lacked soap and disposable towels, were out of children's reach, were few in number, and were unsupervised.

A total of 19,698 telephone calls were made to identify controls; 3497 household members were available. Household members were

asked whether they had visited farm A since September 1 and whether they developed diarrhea within 10 days of the visit; 134 visited the farm during the outbreak, and 22 (16.4%) reported onset of diarrhea within 10 days of the visit. The expected rate of diarrhea from any cause in the general population during a 10-day period is approximately 7% (FoodNet Population Survey, unpublished data, 1998-1999). Because approximately 75,600 persons visited the farm during the outbreak, an estimated 7000 (9.4%) may have developed diarrhea associated with their visit. No further illness was reported after public access to animals was discontinued at farm A.

Washington

During May-June 2000, five persons with culture-confirmed *E. coli* O157 infection were reported to the Snohomish Health District (SHD). Isolates from these persons were indistinguishable by PFGE. Dates of illness onset were May 21-31, and patients ranged in age from 2 to 14 years (median: 7 years); three were male. All five patients reported abdominal cramping and diarrhea, and four reported bloody diarrhea. Three patients, aged 2-6 years, were hospitalized, and one developed HUS. Four patients attending three elementary schools had visited a dairy farm (farm B) on May 18 or 24. The fifth patient had not visited farm B but had developed diarrhea after a sibling became ill following a farm B visit. Approximately 300 persons visited farm B during the outbreak, primarily preschool- and kindergarten-aged children accompanied by adults.

On May 31 and June 1, an investigation of farm B by SHD and the Washington Department of Health revealed that children were allowed to handle young poultry, rabbits, and goats. Goats, chickens, and a calf were kept in pens and could be touched through a fence. Children brought their own lunches and ate approximately 50 feet from the penned animals. Five animal stool samples collected from the farm were tested for *E. coli* O157; all were negative.

Farm B recommended that visitors bring antibacterial wipes to wash their hands; the farm also provided a communal rinse basin. No signs were posted instructing visitors to wash their hands after touching the animals. No further illness was reported after prevention measures were instituted, including distribution of instructional material and installation of handwashing stations with soap and running water.

Reported by: R Gage, MSPH, A Crielly, MS, M Baysinger, E Chernak, MD, G Herbert, A Johnson-Entsuah, MPH, Montgomery County Health Dept, Norristown; G Fraser, C Rinehardt, M Solomon, G Withers, MS, R Berman, MS, Bur of Laboratories, Lionville; M Moll, MD, J Rankin, DVM, Pennsylvania Dept of Health. J Carroll, M Ettinger, MS, S Henderson, M Mismas, D Patel, T Reed, E Smith, J Wozniak, MS, D Toney, PhD, J Pearson, DrPH, Virginia Div of Consolidated Laboratory Svcs, Richmond. J Hofmann, MD, Snohomish Health District, Everett; J Grendon, DVM, J Kobayashi, MD, Washington Dept of Health. Animal and Plant Health Inspection Svc, US Dept of Agriculture. Foodborne and Diarrheal Diseases Br, Div of Bacterial and Mycotic Diseases, National Center for Infectious Diseases; and an EIS Officer, CDC.

Editorial Note:

The outbreaks described in this report were the first reported in the United States to be associated with direct transmission of *E. coli* O157 from farm animals to humans. An estimated 73,500 cases of illness, 2000 hospitalizations, and 60 deaths occur in the United States each year as the result of *E. coli* O157 infection (*2*); many *E. coli* O157 illnesses are associated with ingesting contaminated food or drink. However, during 1996 and 1997, visiting a farm with cows was identified as an important risk factor for *E. coli* O157 infection; 8% of persons aged $\geq$6 years with *E. coli* O157 infection reported visiting a farm with cows during the preceding 7 days compared with 1% of controls (*3*).

Two random-digit-dial telephone surveys of 9000 persons were conducted during 1996-1997 and 1998-1999; 2% reported having visited a petting zoo during the preceding 5-7

days (*4,5*). In 1999 in Ontario, Canada, an *E. coli* O157 outbreak among visitors to a petting zoo resulted in 159 illnesses (*6)*. In the United Kingdom, farm visit-related outbreaks of *E. coli* O157 infections have been reported among children (*7*). Such outbreak have led to the development of guidelines to prevent *E. coli*-related illnesses in these countries (*6,8)*.

Of the 44 state and territorial public health departments responding to a national CDC survey in June 2000, none had laws to control exposure of humans to enteric pathogens at venues where the public has access to farm animals, and no federal laws exist that address this public health issue. Following these U.S. farm-associated outbreaks, CDC, in collaboration with the Zoonoses Working Group, National Association of State Public Health Veterinarians, U.S. Department of Agriculture, Animal and Plant Health Inspection Services, and other groups, drafted measures to reduce the risk for farm animal-human transmission of enteric infections (*Reducing the Risk for Transmission of Enteric Pathogens at Petting Zoos, Open Farms, Animal Exhibits, and Other Venues Where the Public Has Contact With Farm Animals* on page 11).
Before July 1, 2001, comments about prevention measures can be mailed to Strategies, Foodborne and Diarrheal Diseases Branch, Division of Bacterial and Mycotic Diseases, CDC, 1600 Clifton Road, MS A-38, Atlanta, Georgia 30333, or e-mailed to zcn0@cdc.gov.

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Reducing the Risk for Transmission of Enteric Pathogens at Petting Zoos, Open Farms, Animal Exhibits, and Other Venues Where the Public Has Contact With Farm Animals

Information should be provided. Persons providing public access to farm animals should inform visitors about the risk for transmission of enteric pathogens from farm animals to humans, and strategies for prevention of such transmission. This should include public information and training of facility staff. Visitors should be made aware that certain farm animals pose greater risk for transmitting enteric infections to humans than others. Such animals include calves and other young ruminant animals, young poultry, and ill animals.

When possible, information should be provided before the visit.

IGURE 1. CDC investigator examines a calf at farm A — Pennsylvania, 2005

Venues should be designed to minimize risk. Farm animal contact is not appropriate at food service establishments and infant care settings, and special care should be taken with school-aged children. At venues where farm animal contact is desired, layout should provide a separate area where humans and animals interact and an area where animals are not allowed. Food and beverages should be prepared, served, and consumed only in animal-free areas. Animal petting should occur only in the interaction area to facilitate close supervision and coaching of visitors. Clear separation methods such as double barriers should be present to prevent contact with animals and their environment other than in the interaction area.

Handwashing facilities should be adequate. Handwashing stations should be available to both the animal-free area and the interaction area. Running water, soap, and disposable towels should be available so that visitors can wash their hands immediately after contact with the animals. Handwashing facilities should be accessible, sufficient for the maximum anticipated attendance, and configured for use by children and adults. Children aged <5 years should wash their hands with adult supervision. Staff training and posted signs should emphasize the need to wash hands after touching animals or their environment, before eating, and on leaving the interaction area. Communal basins do not constitute adequate handwashing facilities. Where running water is not available, hand sanitizers may be better than using nothing. However, CDC makes no recommendations about the use of hand sanitizers because of a lack of independently verified studies of efficacy in this setting.

Hand-mouth activities (e.g., eating and drinking, smoking, and carrying toys and pacifiers) should not be permitted in interaction areas.

Persons at high risk for serious infections should observe heightened precaution. Farm animals should be handled by everyone as if the animals are colonized with human enteric pathogens. However, children aged <5 years, the elderly, pregnant women, and immunocompromised persons (e.g., those with HIV/AIDS) are at higher risk for serious infections. Such persons should weigh the risks for contact with farm animals. If allowed to have contact, children aged <5 years should be supervised closely by adults, with precautions strictly enforced.

Raw milk should not be served.

The Commonwealth of Massachusetts
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JANE SWIFT
GOVERNOR
WILLIAM D. O'LEARY
SECRETARY
HOWARD K. KOH, MD, MPH
COMMISSIONER

Memorandum

To: Local Boards of Health, Pool Operators
From: Division of Community Sanitation
Regarding: Communicable Disease and Public and Semi-Public Swimming Pool Use
Date: September 4, 2001

This memo is intended to clarify the term "communicable disease" as it is found in 105 CMR 435.00: Minimum Standards For Swimming Pools. Specifically, 435.22(1) restricts an individual with a communicable disease from working at a swimming, wading or special purpose pool and 435.22(3) requires that a sign be posted at the same locations that states, " No person with a communicable disease is allowed to use the pool."

The regulation solely applies to communicable diseases that are transmitted through water. The following common diseases are known to be transmissible through water and individuals who have one of these diseases are restricted from working at or swimming in a pool:

Bacteria:	Virus:	Parasite:
Shigellosis	Hepatitis A	Cryptosporidiosis
Campylobacteriosis		Giardiasis
Salmonellosis		E.coli O157:H7 Infection

These microorganisms are shed in the feces of an infected person. Since the disease-causing organisms can survive outside of the host body and may survive in pool water, the swimmer's health is at risk if contaminated water is ingested. A properly disinfected and pH controlled pool will kill most, but not all, contagious organisms. The Centers for Disease Control and Prevention reports that cryptosporidia oocysts are resistant to chlorine and may remain infective for days in a sufficiently chlorinated pool. It is important that swimmers observe the no swimming rule if they have been diagnosed with any of the diseases noted above or have symptoms that might be due to organisms that cause these diseases. It is recommended that upon recovery, an infected individual wait an additional fourteen days before using the pool. (If you have a question regarding a disease that is not listed and restrictions on pool use, please contact the Division of Community Sanitation at (617) 983-6766.)

It is important to note that although an individual may have a contagious disease, **if that disease cannot be contracted through water, the swimming pool regulation restrictions on pool use**

are not applicable. For example, according to the CDC, there is no evidence that HIV/AIDS is transmissible through water. The virus cannot remain infectious outside of the host body, especially in a well-chlorinated pool that would kill the virus. While HIV is a disease that is contagious, it has been proven contagious only through activities that involve the exchange of infected bodily fluids, such as, in sexual contact and sharing needles with an infected individual; therefore individuals with HIV/AIDS are not restricted from pool use.

Fecal Incident Prevention in Swimming Pools

Division of Community Sanitation

I. FECAL INCIDENT PREVENTION IN SWIMMING POOLS

Although the actual health and safety risks associated with fecal accidents are considered to be minimal, provided that proper pool chemical levels are maintained, fecal incidents do pose a significant interruption in pool operations. As such, prevention of fecal incidents should be stressed. The following preventative measures shall be implemented at all pools:

A. Patrons must be directed to take a cleansing shower before entering the pool.
B. Do not permit diaper changing at poolside. Do not allow young children to be "dipped" or rinsed off in the pool as part of the diaper-changing process.
C. Patrons who are ill or have suffered from diarrhea within the previous two (2) weeks should be denied admittance into the water. It has been shown that persons with cryptosporidiosis continue to shed crypto oocysts (the infectious form of the organism) in their stool for 2 weeks after their diarrhea has ended and can therefore infect others.
D. All persons wearing diapers, or who would be of diaper-wearing age (e.g., infants and toddlers), should wear swimsuit diapers or tight-fitting rubber or plastic pants which will contain fecal matter and prevent it from entering the pool.
E. Do not allow pets in the pool area. *See* 304 CMR 12.08.
F. Maintain the chemical feed equipment and chemicals at optimal levels. This includes maintaining the disinfectant levels (residual chlorine levels between 2.0 and 3.0 ppm); optimal pH (7.4-7.6); alkalinity (80-120 ppm); and calcium hardness (200-400 ppm). Note: Lack of proper pH can greatly affect disinfection effectiveness in chlorinated pools.

II Fecal Incident Procedure in Swimming Areas

There is a concern regarding the potential transmission of *cryptosporidium parvum* (a parasite excreted in the feces of infected humans and other mammals) and *escherichia coli O157:H7* (a harmful strain of coliform bacteria living in the digestive tracts of humans and other animals). Most organisms found in properly chlorinated pool water, including E.coli 0157:H7, are killed very quickly. In fact, usually only a few seconds of disinfection are needed to kill 99.9 percent of these organisms. Those organisms that are more resistant to disinfection, such as cryptosporidia, are typically introduced into pool water via very watery diarrhea. This is seldom noticed or reported. Thus, solid stool is unlikely to contain cryptosporidia. This knowledge thus requires a two-pronged approach to managing a fecal incident.

(The following information was adapted from "Responding to Fecal Accidents in Disinfected Swimming Venues." Morbidity and Mortality Weekly Report, May 25, 2001, Centers for Disease Control and Prevention http://www.cdc.gov/mmwr/pdf/wk/mm5020.pdf*)*

A. Formed stool (solid, nonliquid)

1. Direct everyone to leave all pools into which water containing the feces is circulated. Do not allow anyone to enter the contaminated pool(s) until all decontamination procedures are completed.

2. Remove as much of the fecal material as possible using a net or scoop and dispose of it in a sanitary manner. Clean and disinfect the net or scoop (e.g., after cleaning, leave the net or scoop immersed in the pool during disinfection). Vacuuming stool from the pool is not recommended*.

3. Raise the free available chlorine concentration to 2 ppm (mg/L), pH 7.2–7.5, if it is <2.0 ppm (mg/L). Ensure this concentration is found throughout all co-circulating pools by sampling at least three widely spaced locations away from return water outlets. This free available chlorine concentration was selected to keep the pool closure time to approximately 30 minutes.
4. Maintain the free available chlorine concentration at 2.0 ppm (mg/L), pH 7.2–7.5, for at least 25 minutes before reopening the pool. In the presence of chlorine stabilizers such as chlorinated isocyanurates, a level of 3.0 ppm (mg/L) of free available chlorine must be achieved. Ensure that the filtration system is operating while the pool reaches and maintains the proper free available chlorine concentration during the disinfection process.
5. Establish a fecal accident log. Document each fecal accident by recording date and time of the event, formed stool or diarrhea, free available chlorine concentration at the time or observation of the event and before opening the pool, the pH, the procedures followed to respond to the fecal accident (including the process used to increase free chlorine residual if necessary), and the contact time.

B. Diarrhea (liquid stool)

1. See A1.
2. See A2.
3. Raise the free available chlorine concentration to 20 ppm (mg/L) ¶ and maintain the pH between 7.2 and 7.5. Ensure this concentration is found throughout all co-circulating pools by sampling at least three widely spaced locations away from return water outlets. This chlorine and pH level should be sufficient to inactivate Cryptosporidium and should be maintained for at least 8 hours (one turnover for a standard pool). If necessary, consult an aquatics professional to determine and identify the feasibility, practical methods, and safety considerations before attempting the hyperchlorination of any pool.
4. Ensure that the filtration system is operating while the pool reaches and maintains the proper free available chlorine concentration during disinfection.
5. Backwash the filter thoroughly. Be sure the effluent is discharged directly to waste and in accordance with state or local regulations. Do not return the backwash through the filter. Where appropriate, replace the filter media.
6. Swimmers may be allowed into the pool after 8 hours **and** when the free available chlorine level has been returned to the normal operating range (1.0-3.0 ppm). Maintain the free available chlorine concentration and pH (7.2-7.8) at standard operating levels. If necessary, consult state or local regulatory authorities for recommendations on bringing the free available chlorine levels back to an acceptable operating range.
7. See A5.

* No uniform recommendations for disinfection of vacuum systems are available. However, if a vacuum system is accidentally used, the waste should be discharged directly to a sewer or other approved waste disposal system and not through the filtration system. The dilution effect of the pool water going through the hose may reduce the risk for high-level contamination of the vacuum system.

Many conventional test kits cannot measure free available chlorine levels this high. Use chlorine test strips that can measure free available chlorine in a range that includes 20 mg/L (such as those used in the food industry) or make dilutions for use in a standard DPD (N, N-diethyl- p-phenylenediamine) test kit using chlorine-free water.

August 31, 2001

Bottled Water Products Sold in Massachusetts

Required Testing: An Update

Kim K. Foley, R.S.

This chart summarizes the substances and the levels of disinfectants and disinfectant byproducts for monitoring in source and finished water products as of January 1, 2002:

Water Type	Disinfectant Used	FDA Monitoring Requirement	FDA Monitoring Frequency
Public Water Supply	Ozone, chlorine, chloramine, or chlorine dioxide	No monitoring required if data available from PWS	Annually
Private Source Water: springs, wells, etc.	No disinfectant used at source	No monitoring required for source if no disinfectant used	No monitoring if no disinfectant used Exempt
Private Source Water: springs, wells, etc.	Ozone	Bromate, HAA(5), TTHMs	Annually
Private Source Water: springs, wells, etc.	Chlorine, chloramine, or chlorine dioxide	HAA(5), TTHMs	Annually
Finished Products	Ozone or any chlorine-based disinfectant	Chlorine, chloramine, chlorine dioxide, bromate, chlorite, HAA(5), TTHMs	Annually

On December 16, 1998, U.S. Environmental Protection Agency (EPA) published the Stage 1 Disinfection Byproducts Rule (Stage I DBPR) (63 FR 69390) to address potential public health effects from the presence of disinfectants and disinfectant byproducts (DBP) in drinking water.

The Massachusetts Division of Food and Drugs (DFD) has determined that as part of the annual permit renewal process the above noted parameters will be required on both source and finished bottled water products and treated polished water used for carbonated beverage manufacturing.

There is one exemption allowed for source waters testing; if the source water were a non public water supply which does not treat the water source with a chlorine based sanitizer or ozone, they are exempt from testing the source. Bottlers using a public water supply may submit a statement from the regulating authority stating that the supply meets EPA standards as the disinfectant byproducts rule is a federal standard.

Disinfectants are chemicals, such as chlorine and ozone, that are added to drinking water to control microbial contamination. Both bottlers and public water suppliers may use disinfectants. Public water supplies (PWS) typically add disinfectants to drinking water at levels sufficient to maintain a disinfectant residual throughout the distribution system (i.e., they system of pipes that takes water from the treatment plants to the customers). DBPs are chemicals that result from the unintentional interaction of the disinfectants with the inorganic or organic compounds present in the water supply. Examples of DBPs include chloroform (a byproduct of treatment with chlorine) and bromate (a byproduct of oxonation).

On July 5, 2001, the U.S. Food and Drug Administration (FDA) issued a direct final rule for Disinfectants and Disinfection Byproducts (D/DBP). [Federal Register Notice/Vol. 66, No. 129/ Thursday, July 5, 2001/Rules and Regulations, p. 35373]. This direct final rule will ensure that the minimum quality of bottled water, as comparable with the quality of public drinking water, meets the Environmental Protection Agency's (EPA's) standards.

The FDA is amending its bottled water quality standard regulations by establishing allowable levels for three residual disinfectants (chloramines, chlorine, and chlorine dioxide) and three types of disinfection byproducts (DBPs) (bromate, chlorite, and haloacetic acids (HAA5)). FDA is also revising the existing allowable level for the DBP total trihalomethanes (TTHM) from 0.10 mg/l to 0.080 mg/l. FDA is adopting EPA's maximum contaminate levels for bromate, chlorite, HAA5 and TTHM and EPA's MRDLs (maximum residual disinfection levels) for chloramines, chlorine, and chlorine dioxide as allowable levels for these contaminants in the quality regulations for bottled water. FDA is also adopting the EPA approved analytical methods for monitoring these contaminants in drinking water. Lastly, FDA is adopting an exemption to source water testing (Section 129.35 (a)(4)(iii) if the source water is not from a public water supply and has not been treated with a chlorine based disinfectant or ozone.

FDA has confirmed January 1, 2002, as the effective date for these new parameters. Therefore, all bottled water products, as of January 1, 2002, must meet the FDA's allowable levels for three residual disinfectants (chloramines, chlorine, and chlorine dioxide) and three types of disinfection byproducts: bromate, chlorite, and haloacetic acids (HAA5). Testing must be performed on an annual basis. Regardless of the type of source a bottler is using, FDA is requiring all finished bottled water to test for these DBPs because the potential for disinfectants and DBPs in finished water exists; for example if good manufacturing practices are not followed, such as inadequate rinsing of equipment that has undergone sanitizing operations.

More detailed information can be found in the Federal Register Notice/Vol. 66, No. 129/Thursday, July 5, 2001/Rules and Regulations. Bottlers who have compliance questions can contact the Division of Food and Drugs at 617-983-6700 or the local Board of Health.

This article contains material that is a summary of information provided from both the Federal Register and International Bottled Water Association (IBWA).

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Plant and Dairy Foods and Beverages
August 31, 2001

The Juice HACCP Regulation

Questions & Answers

Final Rule: Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice

(The regulation definitions are included as Appendix 1)

A. Coverage

1. What types of juice and juice products are covered by the regulation?

The regulation applies to juice sold as such or used as an ingredient in beverages. Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree. Juice produced by a person who operates a retail establishment as defined in § 120.3(e) are not covered by the regulation.

The regulation requires that processors apply HACCP principles if they make juice or juice concentrates for subsequent beverage use. Any processor making a product that could be labeled as 100 percent juice or a concentrate of that juice for subsequent beverage use must apply HACCP principles. For beverages containing less than 100 percent juice, only the juice ingredient must be made applying HACCP principles.

2. If I pasteurize my juice, do I need to comply with the regulation?

Yes. All juice processors (except retail processors as defined in the regulation) must comply with part 120 for each type of juice they produce.

3. Does this regulation cover fruit and vegetable purees?

The regulation applies to products sold as juice or used as an ingredient in beverages, including fruit and vegetable purees that are used in juices and beverages.

4. If my juice is sold only within my state, do I need to comply with the new regulation?

Yes. This regulation applies equally to juices produced and sold within the same state as well as juices sold in interstate commerce.

5. When do I need to comply with the juice HACCP regulation?

FDA encourages all juice processors to begin to comply with the regulation as soon as possible. The effective date is January 22, 2002. However, if your firm meets the definition for a small business, the effective date is January 21, 2003. If your firm meets the definition of a very small business, the effective date is January 20, 2004.

6. What are the definitions of a small business and a very small business?

Small businesses employ fewer than 500 persons (§120.1(b)(1)). Very small businesses must meet one of the following three criteria: annual sales of less than $500,000, total annual sales greater than $500,000 but total food sales less than $50,000, or operations that employ fewer than an average of 100 full-time equivalent employees and sell fewer than 100,000 units of juice in the U. S. (§120.1(b)(2)). The size of the business is determined by the magnitude of the corporate operation, not of the business unit.

7. I am a dairy processor who purchases pasteurized apple juice concentrate to make a 5% apple juice beverage and a 15% apple juice beverage. Am I required to comply with the juice HACCP regulation, including the 5-log reduction?

Because you are not making juice as defined by § 120.1(a), you are not required to produce your juice beverage under a HACCP system, although it is highly recommended. However, the juice ingredient (i.e., the pasteurized apple juice concentrate) must have been made under a HACCP program (including compliance with § 120.24).

8. I make a carbonated beverage that contains juice. Am I required to comply with the regulation?

As discussed in the response to question 7, because the carbonated beverage is not "juice" as defined by the regulation, you are not required to produce your carbonated beverage under a HACCP system. However, the juice ingredient of the carbonated beverage must have been made under a HACCP program.

9. I buy pasteurized orange juice concentrate (made under HACCP) and repack the concentrate into large volume bag-in-box containers that I sell to retail businesses to be used in an orange juice dispenser where it is mixed with water and dispensed to the consumer. Do I have to also comply with the regulation?

Yes. Each processor (including the repacker), except the retail processor, must do a hazard analysis and determine whether there are any hazards that are reasonably likely to occur during its process. If a processor identifies any hazards as reasonably likely to occur, it must have a HACCP plan to address those hazards. Because the juice beverage made from the orange juice dispenser is produced at a retail establishment, the seller of that juice is not a processor subject to the regulation. The retail establishment should comply with applicable provisions in the Food Code.

10. Are non-beverage foods that contain juice as an ingredient, e.g., a fruit flavored candy, required to be produced under a HACCP system?

No. The juice HACCP regulation applies to the processing of juice that is sold either as juice or sold for use as a beverage ingredient. Thus, a fruit flavored candy that contains juice as an ingredient is not required to be produced under a HACCP system.

11. Are food ingredients other than juice that are derived from fruit, e.g., citrus oil, required to be produced under a HACCP system?

No, the juice HACCP regulation applies only to the aqueous extract of fruits and vegetables that is sold either as juice or for use as an ingredient in beverages and not to other fruit or vegetable by-products such as citrus oil.

12. Would pulp from a fruit or vegetable used to make a juice or diluted juice beverage be considered juice under the juice HACCP regulation?

Yes. As noted, fruit and vegetable purees used as a juice ingredient are considered "juice" under the regulation. Pulp (i.e., pressed edible fruit or vegetable matter) is often a part of the aqueous liquid stream expressed or extracted from fruits and vegetables (e.g., citrus juice) and is comparable to puree except that it may not undergo the same degree of maceration. Pulp in a juice or a diluted juice beverage is considered juice or a juice ingredient; with a diluted juice beverage, processors are only required to comply with part 120 when making the juice ingredient (e.g., the pulp).

13. Are coffee and tea covered under the regulation?

No. Coffee and tea are infusions produced from dried ingredients and have traditionally not been considered to be juices. Thus, they are not covered under the regulation.

14. Would juice concentrates intended for uses such as flavors or sweeteners in foods other than beverages be subject to the regulation?

Juice concentrates intended for use as flavors, sweeteners, or similar uses in products that are not beverages are not subject to the regulation. However, because there may be problems segregating product used in beverages from that used in other foods, prudent juice concentrate processors should consider implementing HACCP for all of their juice products, not just those products that will be made into juice or used in beverages.

B. Retail Exemption

15. If a retailer decides to pasteurize his apple cider, does he need to have a HACCP system?

Retail producers of juices are not covered by the regulation and would not be required to establish a HACCP system regardless of whether they pasteurize their products.

A retail establishment is an operation that only provides juice directly to consumers. "Provides" includes storing, preparing, packaging, serving, and vending. A retail establishment does not include an establishment that sells or distributes juice to other business entities as well as directly to consumers.

FDA's Food Code provides guidance to retail producers for making safe products.

16. Does the regulation cover apple cider that I make from my own apples and sell over the internet directly to consumers? What about apple cider that I make from my own apples and sell at a farmers market?

If you make cider from your own apples (or apples that you have purchased) and only sell it directly to consumers (e.g., internet sales, farmers markets), you are considered a retailer and thus, your cider does not need to be processed under a HACCP system.

17. If I hire someone to make cider from my apples and I sell this cider at my roadside stand, is this juice producer required to have a HACCP system?

Yes. Only retail establishments are exempt from the regulation. Under the regulation, a retail establishment stores, prepares, packages, serves, and vends its product exclusively and directly to consumers. If someone else processes juice for a retail establishment, that processor is required to operate under HACCP principles.

18. Company A processes juice in a central kitchen and sells the juice to consumers from its own retail outlets. Is Company A's central kitchen considered a retail establishment? Are Company A's retail outlets considered retail establishments?

Company A's central kitchen is not a retail establishment that is exempt from the regulation because it does not sell juice directly to consumers at that location. However, Company A's retail outlets are retail establishments under part 120, if they sell juice directly to consumers and do not sell juice to other business entities (i.e., retail outlets owned by another company).

19. Company B processes juice in a central kitchen that sells juice directly to consumers from its central kitchen as well as supplying its retail outlets. Is the central kitchen a retail establishment? Are Company B's outlets retail establishments?

Company B's central kitchen is a retail establishment under part 120, because it (1) sells juice directly to consumers and (2) does not sell juice to other business entities (i.e., it provides juice only to the retail establishments it owns). If the retail outlets owned by Company B sell juice directly to consumers, but not to other business entities, they are also retail establishments under part 120. FDA encourages central kitchens that are retail establishments under the rule to establish a HACCP system in the processing of juice.

20. If Company C processes juice in a central kitchen that sells juice directly to consumers from its central kitchen and from its retail outlets, but also sells juice to other business entities, is the central kitchen a retail establishment?

Even though Company C sells juice directly to consumers at its central kitchen, the central kitchen is not a retail establishment for purposes of part 120 because it sells juice to business entities that it does not own.

C. Relationship to CGMP's

21. Do FDA's "Current Good Manufacturing Practices" (CGMP) regulations in 21 CFR Part 110 apply to firms that are subject to the juice HACCP regulation? Does compliance by these firms with the juice HACCP regulation replace the need to comply with the CGMP regulations?

D. The Juice Hazard Analysis

22. What is a hazard analysis?

23. Who should conduct the hazard analysis?

24. What is a "hazard that is reasonably likely to occur?"

25. What is the best way to begin a hazard analysis?

26. How do I conduct a hazard analysis?

27. What is a control measure?

28. What is a critical control point?

E. Control Measures

29. When am I required to implement a HACCP control measure?

30. What are some examples of HACCP control measures?

31. If a grower implements FDA's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," also referred to as FDA's Good Agricultural Practices (GAP) guidance document, is it considered a HACCP control measure?

32. If I sell juice in bulk to company X for final processing and packaging of juice, who is responsible for determining whether HACCP controls for chemical and physical hazards are needed for the juice?

33. If I sell juice in bulk to company X for final processing and packaging of a diluted juice product, who is responsible for determining whether HACCP controls for chemical and physical hazards are needed for the juice?

F. The 5-log Reduction Performance Standard

34. What is the 5-log pathogen reduction performance standard?

35. Does a 5-log reduction in the bacterial plate count (i.e., aerobic plate count or total plate count) of a juice sample meet the performance standard requirement?

36. What times and temperatures should I use to pasteurize my juice?

37. How can I achieve a 5-log reduction without pasteurizing the product?

38. May I do the 5-log reduction on the fruit before extracting the juice?

39. May cleaning (i.e., washing of the produce) and culling (i.e., removal of damaged produce) be included among the control measures used to meet the 5-log reduction requirement?

40. May juice be treated in one processing facility to achieve part of a 5-log pathogen reduction, i.e., a 2-log reduction, and then transported to another facility for treatment to achieve the remainder of the 5-log reduction?

41. May I use fruit that has fallen from the tree to the ground (i.e., drops) to make juice?

42. I make shelf-stable juice that receives over a 10,000-log reduction. Am I still required to have microbial control measures in a HACCP plan? What about juice concentrates that are processed with over a 100-log reduction?

43. If I use a heat treatment process on my juice, can I assume that the process meets the 5-log pathogen reduction requirement of the HACCP regulation?

44. If a juice product is treated by a means other than heat to meet the 5-log pathogen reduction requirement, is FDA approval required for the treatment?

45. Does each processor handling a juice have to do a 5-log reduction?

46. If I produce a consumer frozen juice concentrate from a higher concentrated juice that comes from another location via tanker truck (whether or not under direct company control), do I need to redo the 5-log reduction?

47. In the past, some processors have added a small amount of untreated juice to pasteurized juice for flavor enhancement. May I do this?

48. Can a flavor essence recovered during a juice concentration operation be added back to a juice after the juice has received a 5-log pathogen reduction treatment without requiring an additional 5-log treatment?

G. Control Measures for Chemical and Physical Hazards

49. Are there any mandatory HACCP control measures for chemical hazards such as patulin or lead?

50. I am a dairy processor who also makes juice using my milk processing equipment. Should I be concerned about milk residues (allergenic proteins) being present in the juice? What are the controls to prevent possible allergen cross-contamination (cross-contact) in this situation, and should these controls be included in my HACCP Plan??

51. Are HACCP control measures required for any specific physical hazards such as glass?

H. Records

52. What types of records will I be required to maintain to document my HACCP system?

53. How long must I keep the required HACCP records?

54. Are juice processors required to make all of their records related to juice available to FDA inspectors?

55. What records are necessary to show that consumer complaints have been reviewed?

I. Training

56. What specialized training is needed to establish a HACCP system?

57. Does the person(s) doing the key aspects of the HACCP system need to be an employee(s) of the juice processing firm?

J. Imports and Exports

58. Does imported juice that will only be used as an ingredient in beverages have to be produced in compliance with part 120?

59. What are the responsibilities of juice importers under the juice HACCP regulation?

60. Does the regulation apply to juices and juice concentrates produced in the U.S. and intended for export either as bulk shipment or in consumer packages?

61. Are there any established memoranda of understanding (MOUs) for juice? How does someone go about establishing an MOU?

K. Labeling Questions

62. If I want to label my product as pasteurized, what criteria do I need to meet?

63. May I use the warning label statement on my products in lieu of implementing a HACCP system?

64. How can I label my apple cider that is processed using ultraviolet (UV) light ? Can I label it as "pasteurized" or "UV treated?" Can it be called "fresh?"

Appendix 1--Definitions

(a) **Cleaned** means washed with water of adequate sanitary quality.

(b) **Control** means to prevent, eliminate, or reduce.

(c) **Control measure** means any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard.

(d) **Critical control point** means a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.

(e) **Critical limit** means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.

(f) **Culled** means separation of damaged fruit from undamaged fruit. For processors of citrus juices using treatments to fruit surfaces to comply with § 120.24, **culled** means undamaged, tree-picked fruit that is U.S. Department of Agriculture choice or higher quality.

(g) **Food hazard** means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

(h) **Importer** means either the U.S. owner or consignee at the time of entry of a food product into the U.S., or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the U. S. The importer is responsible for ensuring that goods being offered for entry into the U.S. are in compliance with all applicable laws. For the purposes of this definition, the importer is ordinarily not the custom house broker, the freight forwarder, the carrier, or the steamship representative.

(i) **Monitor** means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

(j) (1) **Processing** means activities that are directly related to the production of juice products.

(2) For purposes of this part, processing does not include:

(i) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing and

(ii) The operation of a retail establishment.

(k) **Processor** means any person engaged in commercial, custom, or institutional processing of juice products, either in the U. S. or in a foreign country, including any person engaged in the processing of juice products that are intended for use in market or consumer tests.

(l) **Retail establishment** is an operation that provides juice directly to the consumers and does not include an establishment that sells or distributes juice to other business entities as well as directly to consumers. "Provides" includes storing, preparing, packaging, serving, and vending.

(m) **Shall** is used to state mandatory requirements.

(n) **Shelf-stable product** means a product that is hermetically sealed and, when stored at room temperature, should not demonstrate any microbial growth.

(o) **Should** is used to state recommended or advisory procedures or to identify recommended equipment.

(p) **Validation** means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified food hazards.

(q) **Verification** means those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

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